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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,444	12/21/2001	Kang P. Lee	ASPEN 112 US	1737

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	17

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/034,444	LEE ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 17-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 17-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *07/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the RCE, amendments, IDS and arguments filed 07/12/04. Accordingly claims 2-16 are cancelled and new claims 17-44 are added. Claim 1 is amended. Thus claims 1 and 17-44 are under examination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 17-26, 29-30, 32-39 and 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Berg et al (WO 9501165).

Berg et al teach medical use of organic aerogels and biodegradable organic aerogels, particularly in drug delivery systems. Representative polymers components for aerogel formations include chitin and starch (page 6, lines 6-14). The aerogels are prepared by supercritical drying of the polymer gels. The supercritical drying includes a solvent and the temperature is generally about 31°C (pages 6-7). The aerogels desirably have a density of less than about 90% of that of the corresponding solid, non-porous constituent organic material (page 8, lines 17-21). Aerogels are characterized by low densities and low sound transmission velocities, which provides high and long lasting efficacy, good storage stability. The aerogels also have a preferred particle size of less than 5 microns (page 11). The microparticles may be made by conventional techniques such as milling (page 12, lines 2-10). Presence of lipophilic gases such as

fluorinated alkanes may have a stabilizing effect on aerogels, since these gases will have a lower tendency than air to dissolve in a surrounding aqueous medium (such as body fluid or blood) after administration (page 12, lines 16-25).

Berg discloses that aerogels are suitable for drug delivery systems because of high loading of active ingredients, low toxicity and high efficacy. The medicaments suitable for inclusion into aerogels include anti-inflammatory agents, hormones, etc (page 14, line15 to page 15, line 4). Aerogels may be administered via aerosol delivery. Aerosol formulations are advantageous because of the low density of the aerogels (page 15, lines 5-15). It is also disclosed that the surface of the aerogels may be modified to ensure that material is blood compatible or to affect the absorption of protein (page 16, lines 20-24). The aerogels may be coated with other coatings to increase the stability of the materials (page 17, lines 17-18). Methods of making the aerogels containing the therapeutic agents are disclosed in examples 1-5.

It is shown that Berg et al has disclosed all the recited limitations of the instant claims. Alternatively it would have been obvious to one of ordinary skill in the art to have modified the teachings of Berg et al to make and use the invention as claimed in the instant application because Berg et al is providing sufficient disclosure to one of ordinary skill to make and use the invention and to prepare light, effective, stable and non-toxic particles for drug delivery.

Claims 1,17-18 and 22-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al (WO 9501165) in view of Manning et al (5,981,474).

Berg et al, discussed above, lacks specific disclosure on insulin, methadone and naltrexone as the therapeutic agents for the arogels or that the formulations are for immediate release or slow release.

Manning et al teaches a method of placing a pharmaceutical substance into solution in an organic solvent in the form of a hydrophobic ion pair complex with an amphiphilic material. The particles for delivery to desired targets in the lung should be small in size and preferably propelled by a carrier gas (cols. 1 and 2). Insulin has been prepared by the said solvent system. The suitable pharmaceutical substances include naltrexone, methadone and insulin (col. 5, lines 45-67). The particles are in the size range of 2 to 10 microns, which can get sufficient amount of protein delivered to the lung. This method can be used to treat disorders such as cystic fibrosis, emphysema, etc (col. 8, lines 21-36).

Manning also discloses that incorporation of biodegradable polymers into solid particles may be used to delay release of the pharmaceutical substance (col. 14, lines 30-40).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the formulations and methods of Berg et al by implementing the methods, pharmaceutical agents and particles as taught by Manning

with the reasonable expectations of successfully preparing effective, light and low density particles for delivering insulin, methadone and naltrexone to patients in need of such treatments via inhalation.

Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berg et al (WO 9501165) in view of Rouanet et al (5,864,923).

Berg et al, discussed above, while disclosing low density and high surface area as characteristics of the aerogels, lacks disclosure on the specific density and surface area of the aerogels.

Rouanet et al teaches method of forming aerogels. The method involves contacting a solution containing material to be processed with species selected to precipitate. The material is isolated under supercritical conditions (col. 2, lines 46-53). The particles formed are characterized by their large surface area, low bulk density, high porosity and small particle size. The surface area is between 10 and 1800 m/g. the density is between 0.01 and 0.1 g/cc. The pore size is between 5 and 100 nm and the particle size is between 0.005 and 0.2 microns (col. 3, line 47 to col. 4, line 23). Variety of materials may be processed as aerogels including pharmaceuticals and biological species (col. 9, lines 51-63).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Berg et al on the aerogels for

drug delivery systems and methods of their preparation and use to have looked in the rat for specific disclosures on suitable dimensions of aerogels with the reasonable expectations of preparing effective aerogels for aerosol delivery.

Response to Arguments

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
December 21, 2004